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EXAMINER	
GABEL, GAILENE	
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1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,887	MALYSKA ET AL.	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *10-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-9, filed June 18, 2009 is acknowledged and has been entered. Claims 10-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 1-24 are pending. Claims 1-9 are under examination.

Priority

2. The application claims subject matter disclosed in Provisional Application No. 60/531,645, filed December 22, 2003. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365©. See 37 CFR 1.78(a).

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its

inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentences of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

3. The information disclosure statement filed June 14, 2006 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because pages of references submitted are incomplete. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a). In this case, Novaretti et al., Byrne et al., and Luhong et al. have been submitted with alternating pages missing. Pages 312 and 314 are missing for Novaretti et al. Page 194 is missing for Byrne et al. Pages 36 and 38 are missing for Luhong et al.

Claim Rejections – 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, preamble is ambiguous in reciting, "A method for reducing time to result in immunohematology assay" because it is unclear what is encompassed in the term "result" as recited in the claim.

In claim 1, step a) the abbreviation "RBCs" has not been fully defined. Acronyms or abbreviations should be fully defined at least one time in a given set of claims.

Claim 1, step a) is indefinite in reciting, "continuous agitation" because the term "continuous" is a subjective and relative term that lacks a comparative basis for defining its metes and bounds. See also claims 3 and 4.

Claim 1, step b) lacks clear antecedent in reciting, "the sample" because it is unclear as to whether the recitation refers back to "a sample" in step a) or "a sample incubated or mixed with antigen positive RBCs" in step a).

Claim 1, steps a) and b) are also ambiguous in reciting, "centrifuging the sample…" because step a) fails to specifically define how the sample and the antigen positive RBCs are contained for continuous agitation by an agitation block and subsequently caused to be centrifuged in step b). Should the sample mixture be continuously agitated in a microtube and then poured into a column, i.e. another microtube, having disposed therein the anti-IgG matrix?

Claim 1, step c) is also vague and indefinite in reciting, "reading the result" because it is unclear what is encompassed in the recitation of "result" used in the claim. Does the term result mean "a signal" or "agglutination degree"? Please clarify.

Claim 9 is indefinite in reciting, "wherein the low ionic strength diluent is less than about 0.03M" because it is unclear how the diluent is a parameter. Does Applicant intend, "wherein the low ionic strength diluent is ___"; or alternatively "wherein the diluent has a low ionic strength of less than about 0.03M?"

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2 and 4-8 are rejected under 35 U.S.C. 102(a) as being inherently by Novaretti et al. (Comparison of conventional tube test with diamed gel microcolumn assay for anti-D titration, Clin. Lab. Haem. 25: 311-315 (2003)) in light of Chachowski et al. (US Patent 5,552,064).

Novaretti et al. provide a comparison between conventional tube test and gel microcolumn assay in order to detect red blood cell (RBC) alloantibodies including anti-D titers in RhD sensitized patients (Abstract). For tube testing, a serum sample is obtained from an anti-D alloimmunized patient and then incubated with red blood cells,

i.e. RBCs (red cell suspension) which are RhD antigen positive for 60 minutes at 37 ºC. The RBCs are admixed in a diluent solution having a low ionic strength. Thereafter, the mixture is combined with anti-IgG matrix (monoclonal rabbit antihuman IgG) and then centrifuged for 15 seconds. Result in the form of agglutination or hemolysis is examined and read for graded positive result from 1+ to 4+. For gel microcolumn assay method, a serum sample is obtained from an anti-D alloimmunized patient and then incubated with RhD antigen positive RBCs admixed in a diluent solution having a low ionic strength for 15 minutes at 37 ºC. The RBCs are admixed in a diluent solution having a low ionic strength. Thereafter, the mixture is combined with anti-IgG matrix and then centrifuged for 10 minutes. Result in the form of agglutination or hemolysis is examined and read for graded positive result from 1+ to 4+. The anti-IgG matrix is disposed in a microtube. Accordingly, Novaretti et al. provide that the gel microcolumn assay method has reduced processing time for immunohematology agglutination assays (p. 312, col. 1-2). Novaretti et al. and other literature also provide that the gel microcolumn assay requires small volumes of blood sample, is relatively stable at room temperature with standardized reaction endpoints, making it theoretically an ideal method for prenatal antibody titration studies (p. 313, col. 2).

Although Novaretti et al. is silent in teaching that the sample is mixed with the antigen positive RBCs, Chachowski et al. teach that mixing antigen positive red blood cells with a reagent comprising their corresponding antibodies, i.e. by manual agitation, is required, well known in prior art, conventional, and a standard laboratory practice so

as to allow cell antigen/antibody reactions to take place prior to centrifugation (col. 2, lines 29-41).

Chachowski et al. also disclose a method and device for detecting the presence of blood group antibodies which utilize a matrix of noncompressible microparticles. The method has application in serology and immunohematology (col. 1, lines 11-14). The matrix provides for superior performance in allowing movement of non-agglutinated reactants, especially red blood cells (Abstract). In practice, a serum sample is contacted, mixed, and incubated with antigen positive RBCs (Kell, Duffy, Kidd antigen). The cell mixture is centrifuged in a column containing anti-IgG matrix disposed in a microtube (col. 8, lines 12-26; col. 9, lines 27-34). The anti-IgG matrix comprises glass beads (non-compressible microparticles) (col. 3, lines 45-53; col. 6, lines 1-13). Chachowski et al. provide that gel matrices are also known and used in the art (col. 2, line 65 to col. 3, line 4). The microtube is read and observed for agglutination or non-agglutination (col. 2, lines 6-20).

Accordingly, the teaching of Novaretti et al. in light of Chachowski et al. reads on the claimed invention.

In as far as the recitation of “continuous” in reference to the recitation of “agitation” or “mixing”, it is understood that mixing by shaking a test tube as shown by Chachowski et al. is deemed to be “continuous” in nature in order to effect mixing of the reagent with the sample. Absent a clear definition of what parameters encompass the term “continuous”, it is proper for purposes of this anticipatory rejection to interpret

"mixing" or "shaking" as "continuous agitation" because unpatented claims are given the broadest reasonable interpretation of the term consistent with the specification.

6. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 102(b) as being inherently by Byrne et al. (A Comparison of two column agglutination technologies for routine antibody screening using the indirect antiglobulin technique, British Journal of Biomedical Science 53: 193-195 (1996)) in light of Chachowski et al. (US Patent 5,552,064).

Byrne et al. provide a comparison between two commercial column agglutination technologies for routine antibody screening using indirect antiglobulin technique. The Diamed system uses Sephadex gel and the Biovue system uses minute glass beads. Both systems have incorporated into their gel or glass bead matrices, anti-IgG globulin antibodies (AHG) so as to trap agglutinates and allow unagglutinated RBCs to pass through the matrix into the base of the microtube (Abstract; p. 193, col. 1). Both systems were tested with the RBCs admixed with a low ionic strength diluent, i.e. LISS (p. 193, col. 2). For Diamed microtyping system, heparinized plasma (serum) samples are obtained from patients and then incubated with antigen positive RBCs for 20 minutes at 37 ºC. Thereafter, the mixture is combined with anti-IgG (AHG) matrix in Sephadex gel and then centrifuged for 10 minutes. Result in the form of agglutination is examined and read for graded positive result (p. 194, column 1). For Biovue system, heparinized plasma (serum) samples are obtained from patients and then incubated with antigen positive RBCs for 20 minutes at 37 ºC. Thereafter, the mixture is combined

with anti-IgG matrix in minute glass beads incorporated into a microtubule and then centrifuged for 5 minutes via biphasic spin cycle. Result in the form of agglutination is examined and read for graded positive result (p. 194, column 1). Byrne et al. provide that both procedures gave rapid stable results (p. 194, col. 2). Byrne et al. also teach that agitating (rigorous handling) of the test mixtures is not a problem with both column agglutination technologies (p. 195, col 1).

Indeed, Byrne et al. teach that agitating (rigorous handling) of the test mixtures comprising serum samples and antigen positive RBCs, is not a problem with both gel and glass bead matrices in column agglutination technologies. Chachowski et al. also teach that mixing antigen positive red blood cells with a reagent comprising their corresponding antibodies, i.e. by manual agitation, is required, well known in prior art, conventional, and a standard laboratory practice so as to allow cell antigen/antibody reactions to take place prior to centrifugation (col. 2, lines 29-41). Chachowski et al. is further discussed supra. Accordingly, the teaching of Byrne et al. in light of Chachowski et al. reads on the claimed invention.

In as far as the recitation of "continuous" in reference to the recitation of "agitation" or "mixing", it is understood that mixing by shaking a test tube as shown by Byrne et al. and Chachowski et al. is deemed to be "continuous" in nature in order to effect mixing of the reagent with the sample. Absent a clear definition of what parameters encompass the term "continuous", it is proper for purposes of this anticipatory rejection to interpret "mixing" or "shaking" as "continuous agitation" because

unpatented claims are given the broadest reasonable interpretation of the term consistent with the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Novaretti et al. (Clin. Lab. Haem. 25: 311-315 (2003)) or Byrne et al. (British Journal of Biomedical Science 53: 193-195 (1996)) in light of Chachowski et al. (US Patent 5,552,064).

Novaretti et al., Byrne et al., and Chachowski et al. are discussed supra. Novaretti et al., Byrne et al., and Chachowski et al. differ from the instant invention in

failing to teach that the low ionic strength diluent has an ionic strength of less than about 0.03 M.

However, it is maintained that diluent parameters such as low ionic strength of 0.03M in diluent solvents for incorporation into reagents in immunohematology assays are all result effective variables which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claim 9 is for any particular purpose or solve any stated problem and the prior art teaches use of low ionic strength diluents in compatibility testing, and that parameters may vary according to the sample being analyzed and various matrices being used; absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable range for low ionic strength diluents used in immunohematology methods disclosed by the prior art by normal optimization procedures.

Allowable Subject Matter

8. Claim 3 is free of the prior art. Claim 3 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

August 14, 2009